**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 30, 2014

BioFilm, Inc.
Sherry Castello
Regulatory Affairs Associate
3225 Executive Ridge
Vista, CA 92081

Re: K140590
Trade/Device Name: Astroglide Sensual Strawberry
Regulation Number: 21 CFR§ 884.5300
Regulation Name: Condom
Regulatory Class: II
Product Code: NUC
Dated: September 26, 2014
Received: October 1, 2014

Dear Sherry Castello,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
K140590

Device Name
Astroglide Sensual Strawberry

Indications for Use *(Describe)*

Astroglide Sensual Strawberry is a personal lubricant, for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary
# Astroglide Sensual Strawberry

**General Information on Applicant:**

Applicant: BioFilm, Inc.
3225 Executive Ridge
Vista CA 92081
Phone: (760) 727-9030 Fax: (760) 727-8080

Contact Person: Sherry Castello, Regulatory Affairs Associate
Email: sherry@biofilm.com
Date Prepared: October 30, 2014
510(k) Number: K140590
Establishment Registration: 2025771

**General Information on Device:**

| | |
|---|---|
| **Proprietary Name:** | Astroglide Sensual Strawberry |
| **Common Name:** | Personal Lubricant |
| **Classification Name:** | Condom (21 CFR 884.5300, Product code: NUC, Class II). |

**Predicate Device:** 510(k) Number K122476, Lifestyles® Smooth™ 2-in-1 Massage and Lubricant, Ansell Healthcare Products, LLC; Class II, Product Code: NUC

**Description of Device:** Astroglide Sensual Strawberry personal lubricant is non-sterile, clear, colorless, and water based. It has a subtle flavor and fragrance of strawberry. Astroglide Sensual Strawberry is a proprietary blend consisting mainly of water soluble ingredients similar to the predicate device and other personal lubricant devices currently on the market. This product is not a spermicide or contraceptive. The product is provided in a clear bottle or a tube with flip top cap and it is compatible with natural rubber latex, polyisoprene and polyurethane condoms.

**Indications for Use:** Astroglide Sensual Strawberry is a personal lubricant for penile and/or vaginal application, intended to moisturize and lubricate, to enhance the ease and comfort of intimate sexual activity and supplement the body's natural lubrication. This product is compatible with natural rubber latex, polyisoprene, and polyurethane condoms.

**Technological Characteristics:** There are no fundamental technological differences in Astroglide Sensual Strawberry as compared to the predicate device Lifestyles® Smooth™ 2-in-1 Massage and Lubricant. Both lubricants are non-sterile, water based lubricants with Strawberry flavor and scent. The indications for use are identical and the ingredients are very similar.

**Biocompatibility:** Biocompatibility testing was performed in accordance with ISO 10993, Biological Evaluation of Medical Devices.

- Cytotoxicity, ISO 10993-5: Results show the product is non-cytotoxic
- Guinea Pig Maximization, ISO 10993-10: The product did not elicit any irritation or sensitization reactions.
- Vaginal Irritation, ISO 10993-10: The product was considered non-irritating to the vaginal mucosa in New Zealand White Rabbits as compared to the control article.
- Acute Systemic Toxicity, ISO 10993-11: The product met the requirements of ISO 10993-11. No test animals exhibited any biological reactivity.

**Specifications:** Astroglide Sensual Strawberry has the following lot release specifications: color, clarity, odor, absence of particulate matter, pH, viscosity, total yeast/mold count, total aerobic microbial count, and absence of pathogens including *Staphylococcus aureus, Pseudomonas aeruginosa, and Candida albicans.*

**Other:** This product has been tested for osmolality.

**Shelf Life:** Astroglide Sensual Strawberry shows a shelf-life of 2 years based on an 8 month accelerated stability study and an ongoing real-time stability study. Preservative effectiveness was demonstrated at critical time-points throughout the stability testing. These studies demonstrated that the product specifications were maintained throughout the shelf-life period.

**Condom Compatibility:** Astroglide Sensual Strawberry was tested for compatibility with natural rubber latex, polyisoprene, and polyurethane condoms using ASTM D7661-10, Standard Test Method for Determining Compatibility of Personal Lubricants with Natural Rubber Latex Condoms. Results show that Astroglide Sensual Strawberry is compatible with latex, polyisoprene, and polyurethane condoms.

**Substantial Equivalence:** Astroglide Sensual Strawberry personal lubricant has the same indications for use, similar ingredients, and basic technological characteristics as the predicate device. Astroglide Sensual Strawberry performed well in biocompatibility and stability testing showing it is as safe and effective as the predicate device.